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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,490	02/07/2002	J. Alexander Marchosky	JMA 2977.1	2740

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/071,490	Applicant(s) MARCHOSKY, J. ALEXANDER	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 95-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 95-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>11/14/05</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/19/2005</u> . | 6) <input type="checkbox"/> Other: _____. |

Art Unit: 1618

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination, amendment and remarks filed 10/06/05. Receipt is also acknowledged IDS filed 08/19/05. Claims 91-103 are presented and claims 95-103 will be pending after Examiner's amendment..

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with G. Harley Blosser on 10/31/05 and also on 11/14/05.

The application has been amended as follows:

Claims 1-90 (Canceled)

Claims 91-94 (Canceled)

Claim 95 (Currently amended). A composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid, cancellous bone, demineralized bone matrix, and one or more of a compound selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins, bone material and non-decalcified bone matrix.

Claim 96 (Currently amended). A composition as set forth in claim 95 wherein one or more of the compound is a vascular endothelial growth factor.

Claim 97 (Currently amended). A composition as set forth in claim 95 wherein the bone material consists essentially of bone allograft material.

Claim 98. (Currently amended). A method of inducing bone formation in a vertebrate comprising applying a composition as set forth in claim [91] 95 to a site in a vertebrate where bone formation is desired.

Claim 99 (Currently amended). [A] The method of claim 98 wherein the cancellous bone is present at 10-50% (w/w).

Claim 100 (Currently amended). The method of claim 98 wherein the cancellous bone is milled to 0.1-1.5 mm in its longest diameter.

Claim 101 (Currently amended). The method of claim 98 wherein the hyaluronic acid is present at 10-80% (w/w), the cancellous bone is present at 10-40% (w/w), and the demineralized bone matrix is present at 5-30%.

Claim 102 (Currently amended). A method of inducing bone formation in a vertebrate comprising applying a composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid, cancellous bone, demineralized bone matrix, and one or more compounds selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins, bone material and non-decalcified bone matrix.

Claim 103 (Currently amended). The method of claim 98 wherein the bone material consists essentially of bone allograft material.

The above claims amended claims are pending in the application. The action below is based on claims 95-103 as amended.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/06/05 has been entered.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 95-98, 102 and 103 are rejected under 35 U.S.C. 102(b) as being anticipate by Sander et al. (EP 0 522 569).

Sander disclose a composition for “effecting bone repair” and the composition comprises a matrix that comprises hyaluronic acid (page 2, lines 38-54; page 3, lines 1-29), growth promoting factors, osteogenic agent such as demineralized bone and cancellous bone (page 4, lines 33-42), therapeutic agent such as antimicrobial agents (page 4, lines 24-32). Sander meets

Art Unit: 1618

the limitation of the claims. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

5. Claims 95-98, 102 and 103 are rejected under 35 U.S.C. 102(e) as being anticipated by Muschler (US 6,049,026).

Muschler teaches a composition comprising hyaluronic acid, demineralized bone matrix and cancellous bone. In addition to the components of the composition listed above, the composition of Muschler may also contain fibroblast growth factors, platelet derived growth factors, fibronectin molecules, epithelial growth factors and bone morphogenic proteins. See column 2, lines 28-35 and column 4, lines 4-68. Muschler meets the limitations of the claims. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 95-98, 102 and 103 are rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Sander et al. (EP 0 522 569).

Sander is discussed above. However, in the alternate, these claims Sander renders the claims obvious in light of the suggestion for a bone repair matrix composition that comprises hyaluronic acid (page 2, lines 38-54; page 3, lines 1-29), growth-promoting factors, osteogenic agent such as demineralized bone and cancellous bone (page 4, lines 33-42), therapeutic agent such as antimicrobial agents (page 4, lines 24-32). It would have been obvious to one of

Art Unit: 1618

ordinary skill in the art at the time the invention was made to compose a bone repair matrix from hyaluronic acid or collagen or cellulose ether and tissue growth factors, osteogenic agents and “medico-surgically useful substances.” One having ordinary skill in the art would have been motivated to use the suggested composition of Sanders with the expectation of effecting bone repair.

8. Claims 95-98, 102 and 103 are rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Muschler (US 6,049,026).

Muschler is discussed above and renders obvious the claims in the alternate. Muschler suggests a number of components that comprises implantable bone graft. It would have been obvious to one of ordinary skill in the art at the time the invention was made to compose bone graft according to Muschler. One having ordinary skill in the art would have been motivated to compose the bone graft with the expectation of effectively implanting the graft in a host subject.

9. Claims 99-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander et al. (EP 0 522 569).

Sanders is discussed above. Sanders clearly discloses the composition of the invention. Sander does not disclose the amounts recited in claims 99-101. However, Generally, differences in amounts of hyaluronic acid, demineralized bone and cancellous bone and the length of the cancellous bone will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected results. “W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Art Unit: 1618

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the bone composition of Sander. One having ordinary skill in the art would have been motivated to use the amounts of hyaluronic acid and demineralized bone, and amounts and size of the cancellous that would be effective in bone repair in the subject in need thereof.

Suggestion:

Incorporating claim 100 in claim 95 and providing any evidence of any unexpected result of the size of the bone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

